K133521

Traditional 510(k) Summary

APR 1 1 2014

Submitter: AZE Ltd.
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Date Prepared: April 7, 2014

Establishment Registration Number: 3005664732

Trade Name: AZE Phoenix
Common Name: System, Image Processing, Radiology
Device Classification: Picture, archiving, and communication system
Class: II
Product Code: LLZ
Classification Panel: 892.2050

Predicate Device(s): K060453, VirtualPlace, AZE, Ltd.
K093621, syngo.PET & CT Oncology, Siemens AG Healthcare SY
K123375, syngo.via, Siemens AG Healthcare SY

Device Description: AZE Phoenix is a distributed client-server radiological review station that allows easy selection, review, processing and time-series comparison of multi-modality DICOM-compliant radiological images of patients. The AZE Phoenix software accepts, transfers, displays, stores, and digitally processes DICOM medical images from a variety of diagnostic imaging systems (such as CT, MRI, or image archives) for viewing image manipulation, communication, printing, and quantification. AZE Phoenix queries, retrieves, and sends DICOM compliant radiological images of patients to and from any number of DICOM Picture Archiving and Communication Systems (PACS) images sources. Phoenix collects all retrieved image series from all time-points and imaging modalities associated with a patient in a single patient centric list. Phoenix capabilities include: side-by-side and fusion image display; two-dimensional length, size, and angle measurements; Response Evaluation Criteria in Solid Tumors (RECIST) guideline measurements; image alignment by registration; tagging images to rapidly query and display image; customizable hanging protocol display

	layouts; and the ability to push specific image series to AZE VirtualPlace™ workstation (cleared under K060453) for in depth series specific analysis.
Intended Use:	AZE Phoenix software is intended as a radiological review station and for comparison of medical images from multiple imaging modalities and/or time-points. When interpreted by a trained radiologist the images displayed in Phoenix may be used as a basis for diagnosis. AZE Phoenix supports review and comparison by collecting all image data associated with a patient from disparate data servers, modalities, and time-points in a patient centric data list. Users select images from the patient data list for qualitative visual inspection of individual study images and comparison of aligned side-by-side studies or fused visualizations. Users can also make quantitative anatomical measurements in the images including RECIST guideline measurements and save measurements to track changes over time in graphical plots. After selection and comparison of time-series images, individual images may be loaded into AZE VirtualPlace™ workstation which is launched directly from Phoenix for series specific analysis. In summary, Phoenix enables medical image inspection and diagnosis along with qualitative and quantitative comparison of patient images over time followed by in depth analysis in AZE VirtualPlace™ workstation. AZE Phoenix is not indicated for mammography use. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA-approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.
Technological Characteristics:	Similar technological characteristics to currently marketed predicate device listed above. See comparison table, below.
Performance Testing (Bench):	• Formal software verification and validation • Measurement validation using CD ROM phantom CT images, clinical CT and MRI images comparing subject and predicate (VirtualPlace) geometric measurements, intensity measurements and free drawing RECIST measurements showed no significant differences. • Alignment and fusion image display validation using human breath cycle CT time series images comparing registration methods showed significant improvement in alignment from DICOM header patient orientation information to full registration to liver target registration.
Performance Testing (Animal or Clinical):	None
Substantial Equivalence Rationale:	The technological characteristics and performance data for the AZE Phoenix software demonstrates it is substantially equivalent to the predicate devices. See comparison table, below. The differences in

indications for use for the subject and predicate devices are primarily in the degree of description and are not critical to the intended use of the devices and do not affect the safety or effectiveness of the device when used as labeled.

Technological Comparison of Phoenix vs Predicate Devices

Feature	*Phoenix* (K133521)	*VirtualPlace* (K060453)	*Syngo.PET & CT Oncology* (K093621)	*Syngo.Via* (K123375)
Indications for Use	AZE Phoenix software is intended as a radiological review station and for comparison of medical images from multiple imaging modalities and/or time-points. When interpreted by a trained radiologist the images displayed in Phoenix may be used as a basis for diagnosis. AZE Phoenix supports review and comparison by collecting all image data associated with a patient from disparate data servers, modalities, and time-points in a patient centric data list. Users select images from the patient data list for qualitative visual inspection of individual study images and comparison of aligned side-by-side studies or fused visualizations. Users can also make quantitative anatomical measurements in the images including RECIST guideline measurements and save measurements to track changes over time in graphical plots. After selection and comparison of time-series images, individual images may be loaded into AZE	AZE VirtualPlace is an image processing workstation that accepts, transfers, displays, stores, and digitally processes DICOM medical images from a variety of diagnostic imaging systems (such as CT, MRI, or from image archives) for viewing, image manipulation, communication, printing, and quantification. When interpreted by a trained physician, filmed or displayed images on the VirtualPlace monitor may be used as a basis for diagnosis, except in the case of mammography images. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5M pixel resolution and meets other technical specifications reviewed and accepted by FDA.	Syngo.PET & CT Oncology is a medical diagnostic application for viewing, manipulation, 3D-visualization and comparison of medical images from multiple imaging modalities and/or time-points. The application supports functional data, such as PET or SPECT as well as anatomical datasets, such as CT or MR. Syngo.PET & CT Oncology enables visualization of information that would otherwise have to be visually compared disjointly. Syngo.PET & CT Oncology provides analytical tools to help the user assess, and document changes in morphological or functional activity at diagnostic and therapy follow-up examinations. Syngo.PET & CT Oncology is designed to support the oncological workflow including interpretation and evaluation of examination, and follow up documentation of findings.	Syngo.via is a software solution intended to be used for viewing, manipulation, communication, and storage of medical images. It can be used as a stand-alone device or together with a variety of cleared and unmodified syngo based software options. Syngo.via supports interpretation and evaluation of examinations within healthcare institutions, for example, in Radiology, Nuclear Medicine, and Cardiology environments. The system is not intended for the displaying of digital mammography images for diagnosis in the U.S.

Feature	*Phoenix* (K133521)	*VirtualPlace* (K060453)	*Syngo.PET & CT Oncology* (K093621)	*Syngo.Via* (K123375)
	VirtualPlaceTM workstation which is launched directly from Phoenix for series specific analysis. In summary Phoenix enables medical image inspection and diagnosis along with qualitative and quantitative comparison of patient images over time followed by in depth analysis in AZE VirtualPlaceTM workstation. AZE Phoenix is not indicated for mammography use. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA-approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.			
Input Image	DICOM compliant radiological images	DICOM compliant radiological images	DICOM compliant radiological images	DICOM compliant radiological images
Image Modality(s)	CT, MR, US, PET, SPECT	CT, MR, US, PET, SPECT	CT, PET, SPECT	CT, MR, US, PET, SPECT

Feature	*Phoenix* (K133521)	*VirtualPlace* (K060453)	*Syngo.PET & CT Oncology* (K093621)	*Syngo.Via* (K123375)
Post Processing Techniques	Multiplanar reconstruction (MPR)	Multiplanar reconstruction (MPR)	[Not specified]	Multiplanar reconstruction (MPR)
	Reslice images using interpolation	Reslice images using interpolation	[Not specified]	Reslice images using interpolation
	Segmentation			Segmentation
	Image Registration			Image Registration
	Change slab thickness by intensity averaging	Change slab thickness by intensity averaging		Change slab thickness by intensity averaging
Measurements	Anatomical line measurements • Diameter • Angle • Ratio	Anatomical line measurements • Diameter • Angle • Ratio		
	Region of interest (ROI) • Area • Mean intensity • Intensity histogram	Region of interest (ROI) • Area • Mean intensity • Intensity histogram		Region of interest (ROI) • Area • Mean intensity • Intensity histogram
	Tumor time-point comparison		Tumor time-point comparison	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 11, 2014

AZE, Ltd.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Service, LLC
1394 25TH STREET NW
BUFFALO MN 55313

Re: K133521
Trade/Device Name: AZE Phoenix
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 14, 2014
Received: March 18, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara For

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133521

Device Name
AZE Phoenix

Indications for Use *(Describe)*

AZE Phoenix software is intended as a radiological review station and for comparison of medical images from multiple imaging modalities and/or time-points. When interpreted by a trained radiologist the images displayed in Phoenix may be used as a basis for diagnosis. AZE Phoenix supports review and comparison by collecting all image data associated with a patient from disparate data servers, modalities, and time-points in a patient centric data list. Users select images from the patient data list for qualitative visual inspection of individual study images and comparison of aligned side-by-side studies or fused visualizations. Users can also make quantitative anatomical measurements in the images including RECIST guideline measurements and save measurements to track changes over time in graphical plots. After selection and comparison of time-series images, individual images may be loaded into AZE VirtualPlaceTM workstation which is launched directly from Phoenix for series specific analysis. In summary, Phoenix enables medical image inspection and diagnosis along with qualitative and quantitative comparison of patient images over time followed by in depth analysis in AZE VirtualPlaceTM workstation.

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Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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